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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/720,462

11/24/2003

Thomas J. Boyd

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,462	Applicant(s) BOYD ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16-22 and 24-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-22 and 24-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02 Feb 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed March 4, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Objections (New Objection)

Claims 36 and 55 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite the limitation "a water soluble hydroxyalkyl cellulose polymer", which is broader than the recitation of "a water soluble hydroxyalkyl methyl cellulose" recited in the independent claims. Thus the claims are not further limiting in regards to the hydroxyalkyl cellulose polymer.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

1) Claims 16-19, 24, 28-32, 34-37, 40-42, 47, 52 and 55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 4,440,877).

Applicant's Arguments

Applicants have amended claims 16 and 37 to reflect that the hydroxyalkyl cellulose of the flakes is a hydroxyalkyl methyl cellulose. Applicant argues Hauschild teaches very specific agglomerate speckles containing a functional material and binders, wherein the binders are a mixture of ethyl cellulose and a water soluble binder. In contrast, the present invention is directed to oral compositions containing flakes which comprise a water soluble hydroxyalkyl methyl cellulose polymer. The skilled artisan would actually be led away from Applicants' presently-claimed invention, for the presently-claimed invention requires methyl cellulose. Because Hauschild teaches the requirement of ethyl cellulose, rather than methyl cellulose, the skilled artisan would have no reasonable expectation of success in arriving at the presently-claimed invention. Applicants therefore submit that Hauschild does not render obvious the present claims. This argument is not persuasive.

Examiner's Response

As previously stated in the previous Office Action mailed November 13, 2008, the claims use open language "comprising" which indicates other components, such as insoluble polymers, may also be included in the flakes. The claims do not recite functional limitations that would exclude ethyl cellulose from being present. The

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reference does not teach away from the compositions because as stated above, the claims do not indicate that ethyl cellulose is excluded from the recited flakes and further the reference teaches water soluble polymers. Although the reference does not explicitly say that a hydroxyalkyl methyl cellulose is used as one of the water soluble polymers, it does disclose in the comparative examples that hydroxypropyl methyl cellulose (HPMC) is used in making speckles and carboxymethyl cellulose (CMC), which is disclosed as being a suitable water soluble polymer for using in combination with ethyl cellulose, is used as well. HPMC was shown to yield better results than CMC and therefore it would be reasonable for one of ordinary skill in the art to use HPMC as the water soluble polymer in combination with ethyl cellulose because it yields better results as compared to CMC in regards to the disclosed physical results. HPMC is also disclosed by the art as a water soluble polymer used to make films, as is carboxymethyl cellulose and polyvinyl pyrrolidone (Leung et al., US 2001/0022964). Therefore it would have been obvious to use HPMC in combination with ethyl cellulose to arrive at the presently claimed invention.

2) Claims 14, 15, 20-22, 25-27, 38, 39 and 43-54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hauschild et al. (US 4,440,877) in view of Rajaiah et al. (US 2002/0187108). The rejection is maintained. Claim 15 is cancelled.

Applicant's Arguments

See Applicant's arguments above in regards to Hauschild. Applicant further argues that the Rajaiah reference does not remedy the deficiencies of Hauschild. When read as a whole it does not teach that a composition as taught by Hauschild could be successfully prepared without using ethyl cellulose. Rajaiah does not provide any teaching or suggestion that methyl cellulose could be successfully used. The combination of references does not provide the skilled artisan with any reasonable expectation of success in arriving at Applicants' claimed invention. This argument is not persuasive.

Examiner's Response

See Examiner's Response above in regards to Hauschild. Further, Hauschild discloses water soluble polymers may be used in combination with ethyl cellulose. The claims as presently recited do not exclude ethyl cellulose from being present film flakes of the instant claims. Rajaiah is used to disclose different therapeutic agents that may be used as functional materials in the speckles of Hauschild. Therefore the rejection is maintained.

Claims 14, 16-22 and 24-55 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **LEZAH W. ROBERTS** whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612